Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
7 August 2015

Minutes – item no. 1

Centre 0148 (Shropshire and Mid-Wales Fertility Centre) – Interim Inspection Report

Members of the Panel:	Paula Robinson Head of Business Planning (Chair) Hannah Verdin Head of Regulatory Policy David Moysen Head of IT
Members of the Executive in attendance:	Dee Knoyle Committee Secretary

Declarations of interest: members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of Application

1. The panel noted that Shropshire and Mid-Wales Fertility Centre provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 30 November 2017.

3. The panel noted that the interim inspection took place on 12 May 2015.

4. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 January 2014 to 31 December 2014 showed the centre's success rates were in line with the national average.

5. The panel noted that in 2014, the centre reported seven cycles of partner insemination with two clinical pregnancies. This was in line with the national average.

6. Between 1 January 2014 and 31 December 2014 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%: this means that the centre's multiple live birth rate is likely to be higher than the 10% maximum target for this period. The centre have taken positive steps to address this issue and have recently undertaken a review of their multiple birth minimisation strategy in order to identify patients who may be more at risk of a multiple birth. In consideration of this engagement and action, no recommendations were made in respect of the centre's multiple births minimisation strategy. However the panel noted that the centre's multiple pregnancy rates will be kept under review.

7. The panel noted that at the time of the interim inspection on 12 May 2015, one critical, two major and two other areas of non-compliance were identified. The panel noted in particular the critical non-compliance relating to the provision of suitable and safe facilities. The panel noted that when considering its recommendation to the panel, the inspectorate had taken into account the Person Responsible's (PR) response to the report and recommendations, and the evidence provided by the PR and the Trust management team following a formal management review meeting. The panel noted that the centre has provided evidence of effective implementation of the recommendations relating to the critical area of non-compliance; a commitment to the implementation of the other recommendations; and assurance that the PR has the full support of the Trust with respect to the provision of resources to ensure on-going compliance.

8. The panel noted that in light of the evidence provided, the Executive is satisfied that the PR is likely to discharge his duty under section 17(1)(d) of the HF&E Act 1990 (as amended) to secure that the centre's premises are suitable, and that the inspectorate recommends the continuation of the centre's treatment and storage licence.

Decision

9. The panel had regard to its decision tree.

10. The panel noted that there were serious concerns arising from the critical area of non-compliance relating to the provision of suitable and safe facilities. However the panel also noted that the centre responded promptly to the inspectorate's recommendations and that whilst further action for remedial works is undertaken, there are no on-going risks to the safety of centre staff or gametes and embryos. The panel commended the PR and the Trust for the swift response to the inspectorate's recommendations in relation to this critical non-compliance, and noted that a full, well resourced, implementation plan is in progress, for completion by the end of October.

11. The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

Signed: Date: 17 August 2015
Paula Robinson (Chair)

Interim Licensing Report

Centre name: Shropshire and Mid-Wales Fertility Centre
Centre number: 0148
Date licence issued: 01 December 2013
Licence expiry date: 30 November 2017
Additional conditions applied to this licence: None
Date of inspection: 12 May 2015
Inspectors: Louise Winstone (Lead), Janet Kirkland-MacHattie and Grace Lyndon (HFEA observer)
Date of Executive Licensing Committee: 7 August 2015

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers and the individuals who deliver that care.
- **Patient experience**: understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection, and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Committee

The Executive Licensing Committee (ELP) is asked to note that at the time of inspection, there were five recommendations for improvement in relation to one critical, two major and two other areas of non compliance as follows:

Critical areas of non compliance:

- the PR should ensure that the centre has suitable and safe facilities to carry out licensed activity.

Major areas of non compliance:

- the PR should ensure compliance with medicines management regulations with regards to alterations in the controlled drugs record book.
- the PR should ensure that CE marked medical devices are used wherever possible.

Other areas of practice that require improvement:

- the PR should ensure that the centre's website meets the requirements of Chair's Letter CH (11)02.
- the PR should ensure that actions are taken to address the complaints about the respect for privacy and dignity received from patients regarding the sperm production room.

The inspection team did not have enough information on which to make a recommendation on the continuation of the centre's licence on the basis of the initial inspection findings and as a consequence, management review meetings were held on 4 and 16 June 2015 in accordance with paragraph 4.6 of the HFEA's compliance and enforcement policy. In relation to the critical area of non compliance referenced above it was concluded that there may be an on-going risk to the safety of patients, staff and the gametes and embryos in storage at the centre. In accordance with paragraph 4.4 of the HFEA's compliance and enforcement policy it was agreed that formal action was warranted.

On the 30 June 2015, a meeting was held at the HFEA with the centre's inspector, the HFEA's Chief Inspector, the PR, Licence Holder (LH) and other key Trust staff members.

This provided an opportunity for clarification of HFEA expectations and requirements. Subsequent to this, the PR and the LH provided a response to this report and accompanying evidence.

The Executive has considered the evidence provided by the PR and the Trust management team during the formal meeting and in responding to this report. It is considered that the centre has provided the following:

- evidence of effective implementation of the recommendations relating to the critical area of non compliance;
- a commitment to the implementation of the other recommendations;
- assurance that the PR has the full support of the Trust with respect to the provision of resources to ensure on-going compliance.

In the course of discussions, the PR was also able to explain that the decision not to alert the HFEA to concerns about the safety of the cryostore until the day of inspection was taken because the PR was confident that there was no actual risk to the provision of liquid nitrogen.

As a result of these interventions, the Executive is satisfied that the PR is likely to discharge his duty under section 17(1)(d) of the HF&E Act 1990 (as amended) to secure that the centre's premises are suitable.

Based on the evidence provided, the inspection team recommends the continuation of the centre's licence.

Information about the centre

The Shropshire and Mid-Wales Fertility Centre is part of The Shrewsbury and Telford Hospital NHS Trust. The centre has held a Treatment and Storage licence with the HFEA since 1994.

The centre provides a full range of fertility services to NHS and private patients.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes as they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 January 2014 and 31 December 2014 show the centre's success rates are in line with the national average.

In 2014, the centre reported a total of 7 cycles of partner insemination with two clinical pregnancies. This is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 January 2014 and 31 December 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 18%: this means that the centre's multiple live birth rate is likely to be higher than the 10% target. The centre have taken positive steps to address this issue and have recently undertaken a review of their multiple birth minimisation strategy in order to identify patients who may be more at risk of a multiple birth. In consideration of this engagement and action, no recommendation has been made in respect of the clinic's multiple births minimisation strategy but the centre's multiple pregnancy rates will be kept under review.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but discussions with staff and a review of the centre's recent audit of witnessing, indicated that the centre has a witnessing system that is compliant with HFEA requirements.

Consent to the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics as it can enable patients to preserve their fertility prior to undergoing other medical treatment

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[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

During the inspection we evaluated the centre's processes for storing gametes and embryos and these were compliant with HFEA requirements.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival and the atmosphere in the clinic appeared calm at all times.

The centre currently have two members of laboratory staff on maternity leave however evidence was provided that the centre do undertake a regular review of staffing levels and are currently recruiting to the post of Quality Manager.

Quality Management System (QMS)

It is important that clinics audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any changes that are identified as required are made as this helps ensure that clinics continuously improve.

The effectiveness of the centre's QMS was assessed by evaluating a sample of the centre's audits. We also considered whether the clinic's processes for implementing learning are effective.

The centre's audits of documentation of witnessing, consent to storage and medicines management were reviewed during the inspection. The inspection team considered that the centre's audit practices are compliant with HFEA requirements.

In the course of the inspection the centre's actions with respect to implementation of HFEA guidance in relation to the following were observed and/or discussed: use of CE marked media and plastic ware; audit of legal parenthood consents; use of revised HFEA consent forms released on 1 April 2015; website content and screening requirements.

The centre is broadly effective in implementing learning from guidance from the HFEA, with one exception. The centre's website is not compliant with the requirements of the Chair's letter CH (11)02 in the following areas;

- Data relating to live birth rates is not less than three years old (see recommendation 5).

Medicines Management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection the centre's processes for medicines management and the safe storage disposal and administration of medicines were reviewed and found to be partially compliant with guidance with the following exception:

- in two instances alterations in the controlled drugs book did not comply with The Misuse of Drugs Regulations, 2001. The Misuse of Drugs Regulations 2001 state 'that no cancellation, obliteration or alteration of any such entry shall be made and a correction of such an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made' (see recommendation 2).

Infection Control

Having suitable arrangements in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections.

During the inspection we assessed compliance with infection control guidance by observation, and found that the centre's procedures were compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment to ensure the safety of gametes and embryos and patients. Approval of such products is denoted by the issue of a "CE mark".

In the course of the inspection the CE mark status of a sample of the medical devices used by the clinic was reviewed. The centre is broadly compliant with HFEA requirements to use CE marked medical devices wherever possible (see recommendation 3). The following medical device used by the centre is not CE marked: tubes used for follicular aspirates during egg collection.

Patient experience

During the inspection visit we spoke to two patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 31 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 22 of the individuals providing written feedback commenting that they had compliments about the care that they received and that staff were caring and supportive.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- have staff that have been noted as kind, caring and supportive.

Complaints have been received however both in feedback provided directly to the HFEA and in feedback received from patients on the day of inspection, regarding the suitability of the sperm production room (see recommendation 4).

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- the two cryostore rooms were considered to be unsafe because standard safety procedures had not been observed. There were no safety signs on the door to one of the rooms, no seal to the doors and no viewing panels in the doors. There was no ventilation or low level extraction fans in either of the rooms (see recommendation 1). In addition, on the day of the inspection the PR advised that the centre had been issued with a three-month notice of withdrawal of supply of liquid nitrogen as a result of failure to meet Health and Safety guidance;
- on the day of inspection the centre was untidy, cluttered and patient notes were in bundles on the floor in some of the offices. There were two filing cabinets, a chair and boxes in the main corridor which is the primary fire escape route. The PR has assured the inspection team that this was rectified post inspection therefore no recommendations have been made but the PR is urged to ensure that the fire exits remain clear and that patient notes are stored appropriately and that the premises are maintained free from slip and trip hazards.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013 recommendations for improvement were made in relation to four major and five 'other' areas of non compliance. The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On going monitoring of centre success rates and risk tool alerts

Since the last inspection in May 2013, the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre's submission of information is compliant with HFEA requirements.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable,

to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the full audit to the HFEA within the required timeframe. The centre's audit had been performed according to the method specified by the HFEA and the centre has acted upon their findings.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. The cryostore premises were not safe or suitable. (SLC T17)	The PR took immediate action to address the safety issues identified on inspection. Subsequent to the inspection, the PR and the Trust management team have developed and submitted a rescue and action plan, documenting the timescale for the implementation of the remedial work to ensure that both the cryorooms are fit for purpose. All staff at the centre have received appropriate safety evacuation training and	The Shrewsbury and Telford Hospitals NHS Trust (SaTH) has committed approximately £225,000 in emergency capital funding to enable urgent works to be performed that will include: moving the cryostore to a new area (with an external wall); siting a large liquid nitrogen storage vessel oustide and piping nitrogen into the room; installing new low level emergency extract facilities, and; installing new aluminium flooring. These works will also require the formation of a new scan room that, following a switch of rooms will be placed where the cryostore currently is sited (See Appendix 1). A programme of works has been developed that should lead to the full completion of works by the end of October 2015.	Remedial action taken on the day of inspection mitigated immediate concerns about the operational safety of the cryostore. Action taken in the time since the inspection has secured official notification of the on-going supply of liquid

	training in the use of rescue equipment. The PR must keep the centre's inspector regularly updated on further progress in implementing the action plan.	We appreciate the understanding of the HFEA with regard to the timescales necessary for such a large scope of works. We have received written confirmation that liquid nitrogen will continue to be supplied during this period, and the Trust has agrred with the supplier procedures to enhance safety during delivery. Both current cryostorage rooms do have high level ventilation which is sufficient to remove 5 times the expected nitrogen boil off rate from the storage vessels. Notice of potential withdrawal of the liquid nitrogen supply was made by the company that supply the product on the 16/4/15 (see 'Timeline' - Appendix 2). The concern of low level 'emergency' ventilation had been on the Trust's risk register, though with a lower risk rating than currently is appreciated. This risk was re-assessed and became the highest risk in the Trust on the day of inspection, when it was shared by myself with the HFEA. Thus, the Trust was taking action to address the issues prior to the inspection. Finally, while both doors to the cryostorage rooms had signs stating 'Strictly no admittance to unauthorised personel', the secondary cryostorage room did not have a sign stating 'Liquid nitrogen- asphyxiant'. This was addressed immediately, on the day of the inspection. New doors were fitted the day after the inspection. The HFEA will be kept informed of further progress as it takes place.	nitrogen. While further action is being taken by the centre to undertake further remedial works, there are no on-going risks to the safety of centre staff or gametes and embryos.

‘Major’ area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. There were two instances noted on reviewing the controlled drugs record book where the amount of medication administered to a patient had been altered. The Misuse of Drugs Regulations, 2001.	The PR should take immediate action to ensure that alterations to the controlled drugs record book are made in accordance with regulations. In responding to this report, the PR should inform the centres’ inspector of the actions that have been taken. Within three months, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit detailing the corrective actions with evidence supporting their implementation should be supplied to the centre’s inspector by 21 July 2015.	We have addressed this issue and will ensure full compliance with HFEA guidance in the future. Our drug record book is routinely audited by the Trust's pharmacy department and the most recent audit found no discrepancies (see Appendix 3). Please may we highlight a difference in the guidelines from different professional groups/bodies, and request your guidance on this matter: The department of Health's 'Safer use of controlled drugs - A guide to good practice in secondary care' states that "If a mistake is made, it should be bracketed in such a way that the original entry is still legible." The Nursing and Midwifery 'Standards for medicines management' state that "If a mistake is made, it should be	No further action required. The centre’s inspector will continue to liaise with the PR on the most suitable method for making alterations to the controlled drugs record book.

		crossed out with a line or bracketed in such a way that the original entry is still legible." The Royal Pharmaceutical Society's guidance 'Medicines, Ethics and Practice - The professional guide for pharmacists' states that "Entries must not be cancelled, obliterated or altered. Corrections must be made by dated marginal notes or footnotes."	
3. The centre had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical devices. The tubes used for follicular aspirates during egg collection are not CE marked. (SLC T30)	In responding to this report, the PR should advise the centres' inspector of the actions taken to ensure compliance with CE marking for medical devices.	This point is made in reference to the use of 'nunc' 14ml round bottomed tubes for egg collection that are not CE marked. The centre has previously audited plastics use in an attempt to rule out the use of all non 'CE' marked disposables where CE marked alternatives are available. Confusion may have arisen as the tubes are 1-Cell MEA tested and LAL tested (common tests for embryotoxicity) but are not CE marked. We have now sourced an alternative which will be used in the future. We are committed to using 'CE' marked disposable where they are available.	No further action required.

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. The PR should ensure that actions are taken to address the complaints about the respect for privacy and dignity received from patients regarding the sperm production room. (SLC T17)	The Inspectorate is aware of the centres’ plans to provide a more suitable sperm production room; however this is not currently in use as the PR is waiting to receive funding for a door keypad. The PR should inform the HFEA when this room is ready to be used when responding to this report.	We are acutely aware of the difficulties regarding our sample production facility. We are awaiting the fitting of new double doors and a key-coded lock that will enable us to use a room with considerably greater privacy. We expect this issue to be resolved in the next 3 months and will update the inspectorate when this issue is closed.	Further action required.
5. The centre’s website is not compliant with the requirements of Chair’s letter CH (11)02 ‘Responsible use of websites: duty of centres’ as the data is not less than three years old. CH (11)02	The PR should inform the HFEA of actions that can be taken to ensure that the centre’s website is compliant with requirements when responding to this report.	The website would normally be updated by the Centre's 'Quality Manager'. Unfortunately at the time of inspection this post was vacant. One set of data was thus 3 months beyond the allowable timescale. The website has been updated to address this and the department has appointed a Quality Manager who will start work in September.	No further action required.

Additional information from the Person Responsible
Our hospital Trust has been developing plans to obtain new and improved premises for the department for over 6 years. The latest iteration of the plan is enclosed (Appendix 4). The Trust has reassured the inspectorate that they will work with the department to obtain a long term solution to the accommodation issues that we have. Finally, on the day of inspection the team were informed that we were awaiting shelving in a room that had been redesignated as a 'notes store'. These patients' notes were kept in bundles and in boxes whilst the change was completed. This 'snapshot' of the department at a time of significant change is not representative of the department during 'normal' working. Shelving has now been fitted within the dedicated notes store..